#8 2/21/03

Docket No. 13761-7016

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a))

[ ] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington D.C. 20231.

[X] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner Lisa Cook at Facsimile No. (703) 308-4242 at 4:30 a.m./p.m.

Dated: February 18, 2003 Name of Person Certifying: Peggy Nichols
Printed Name: Peggy Nichols

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Paul C. Denny, et al.

Assignee: University of Southern California

Filing Date: August 14, 2001

Examiner: Lisa Cook

Serial No.: 09/929,293

Group Art Unit: 1641

Title: SALIVA-BASED METHODS FOR PREVENTING AND ASSESSING THE RISK OF DISEASES

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. § 121

Dear Sir:

On December 30, 2002, a Requirement for Restriction under 35 U.S.C. § 121 was issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the Requirement for Restriction originally was due January 30, 2003. Enclosed herewith is a Petition for a One Month Extension of Time and authorization to charge the fee due to the undersigned's Deposit Account. In view of the filing of this Petition and payment of the fee, a response is now due February 28, 2003. Accordingly this response is timely filed.

Requirement For Restriction Under 35 U.S.C. § 121

In the restriction issued December 30, 2002, the pending claims were alleged to describe the following independent and district inventions:

I. Claims 1-31, drawn to a method of predicting the risk of a disease via the isolation and quantification of mucin in a saliva sample, classified in class 436, subclass 7.1; and

II. Claims 32-60, drawn to a method of reducing risk of a disease via mucin detection and the administration of a therapeutic reagent to a subject further employing oral fluid standards, classified in class 424, subclass 93.1; and

III. Claims 61-71 are drawn to a diagnostic kit for detecting a disease, classified in class 422, subclass 61.

The Office alleged that the inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated because it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case, each of the Groups are patentably distinct because they are allegedly directed to different methods having different functions (Group I – predicts the risk of disease and Group II – reduces the risk of a disease).

The Office argued that the invention of Group I is directed to a method which merely detects a component in isolated mucin as a measure of predicting a disease, while Group II is drawn to therapeutic administration of a reagent wherein a component of mucin is correlated with oral fluid standard thereby reducing the risk of a disease. Further the Examiner indicated that the methods have different method steps and utilized diverse reagents, e.g., Group I does not require therapeutic administration or oral standards.

The Office also alleged that the inventions Group III and (Group I – Group II) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case the kit/product of invention Group III can be practiced with either of the materially different process of Group I or Group II.

The Office alleged that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for Groups I, II or III are not coextensive, restriction for examination purposes as indicated is proper.

Traversal of Requirement for Restriction

Applicants' undersigned attorney, on behalf of Applicants, hereby elect with traverse to prosecute the invention of Group I, claims 1 to 31, drawn to a method of predicting the risk of a disease via the isolation and quantification of mucin in a saliva sample. Applicants expressly reserve the right under 35 U.S.C. § 121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application, or an application claiming the benefit of this application under 35 U.S.C. § 120.

Applicants also respectfully traverse the grounds for restriction and requests reconsideration and withdrawal of the restriction among Groups I to III, claims 1 to 71. There are two criteria for a proper requirement for restriction, namely, (1) the inventions must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction is not required. Under M.P.E.P. § 808, the Examiner must examine the subject application on the merits even though it includes claims to distinct inventions, if the search and examination of the application can be made without serious burden. Applicants maintain that the inventions of claims 1 to 71 are not independent or distinct as each claim in Groups I to III relates to the detection of mucin.

Applicants further maintain that restriction among claims 1 to 71 is improper. First, it would not be a serious burden on the Examiner to search and examine the inventions of Groups I, II and III because each requires the detection of mucin. Applicants further point out that the inventions of claims 1 to 71 in each of the claims of Groups I, II and III are related in function since each relates to detecting the level of mucin. Further, pursuant to MPEP § 802.1, "independent (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect . . ."

Clearly, there is a disclosed relationship between the methods of Groups I, II and III. (See above).

Finally, a search of the inventions of Groups I through III would not impose a serious burden on the Examiner as each relates to the detection of mucin.

In the event the Office maintains the requirement for restriction among the claims of Groups I to III, Applicants' undersigned attorney respectfully requests that the restriction be made final and the procedure of M.P.E.P. § 821.01 be made of record.

Change of Firm Name

The undersigned attorneys' advises the office of a change in firm name to Bingham McCutchen, LLP.

CONCLUSION

No additional fee is deemed necessary in connection with the filing of this Response. However, if the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2518**, referencing billing number **13671-7016**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Should a telephone advance prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 849-4950.

DATE: Feb. 18, 2003

Respectfully submitted,

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